

improvement from baseline to week 26, in 7 of 8 SF-36 domains, versus non-responders, and 2 to 8 times greater improvement in HAQ. Patients attaining low disease activity (Sub-group C) experienced the greatest differences. For Sub-group B, where cohorts had the most comparable baseline scores, results were statistically significant for HAQ ($p=0.0012$) and 6 of 8 SF-36 domains ($p<0.01$ except role-emotional and mental health domains). **CONCLUSIONS:** Patients able to attain T2T-related response achieved significantly greater absolute improvement in health status versus non-responders, in HAQ and 6 of 8 SF-36 domains. There may be additional value in adding change scores to threshold values in current T2T objectives for severe patients and consideration of patient functionality may be warranted.

PMS51

SHARED DECISION MAKING BETWEEN PATIENTS AND PHYSICIANS IN THE CHOICE TO INITIATE BIOLOGIC THERAPY FOR TREATMENT OF RHEUMATOID ARTHRITIS

Bolje S¹, Schenkel B¹, Ramesh V², Ingham M¹
¹Janssen Scientific Affairs, LLC, Horsham, PA, USA, ²Kantar Health, New York, NY, USA

OBJECTIVES: To describe the shared decision-making process between patients and physicians when initiating biologic therapy for the treatment of rheumatoid arthritis (RA) from the patient perspective. **METHODS:** Patients self-reporting a diagnosis of RA completed a self-administered, internet-based questionnaire in the Fall of 2011. A subset of patients currently using a biologic therapy to treat their RA provided details about the decision-making process for initiating their current therapy. **RESULTS:** A total of 2138 respondents (76% female, mean age 56.4) completed the questionnaire. Of these, 20% ($n=434$) were currently being treated with biologic therapy. Discussions about biologic therapy were most often initiated by a rheumatologist (91%); only a small proportion of patients reported that a primary care physician (4%), the patient themselves (3%), or another (2%) initiated the discussion. During the discussions, physicians most often focused on administration (77%), dosing schedule (77%), side effects (71%), safety risks (64%), importance of long-term use (57%), and importance of concomitant methotrexate use (53%). Patients rated the following as very or extremely influential (4 or 5 on a 5-point Likert scale) on the final decision to initiate biologic therapy: advice or recommendation by physician (76%), co-pay assistance to cover out-of-pocket costs (31%), advice or recommendation from other healthcare professional (28%), patient literature materials from physician office (27%), and information from general websites (22%). Most patients (71%) reported making the decision to start biologic therapy at the time of the initial discussion with their physician; mean time for all patients to make a decision to start biologic therapy was 12.2 days from the time of initial discussion. **CONCLUSIONS:** Rheumatologists are best positioned to ensure that patients have the necessary information to actively engage in the shared decision-making process for initiating biologic therapy. Future research should focus on potential outcomes benefits of shared decision-making.

PMS52

VALIDATION OF REMISSION OF RHEUMATOID ARTHRITIS BY TRADITIONAL DISEASE ACTIVITY SCORE AND PROVISIONAL CRITERIA BY AMERICAN COLLEGE OF RHEUMATOLOGY AND EUROPEAN LEAGUE AGAINST RHEUMATISM: ANALYSIS BASED ON PATIENT REPORTED OUTCOMES FROM 3 PHASE III CLINICAL TRIALS OF GOLIMUMAB

Han C¹, Keystone E², Fleischmann R³, Smolen JS⁴, Emery P⁵, Genovese M⁶, Doyle M⁷, Hsia E⁷

¹Johnson & Johnson Pharmaceutical Services, LLC, Malvern, PA, USA, ²Mount Sinai Hospital, Toronto, ON, Canada, ³University of Texas, Dallas, TX, USA, ⁴Medical University of Vienna and Hietzing Hospital, Vienna, Austria, ⁵University of Leeds, Leeds, UK, ⁶Stanford University, Palo Alto, CA, USA, ⁷Janssen Research & Development, LLC, Spring House, PA, USA

OBJECTIVES: Remission by Boolean-based definition (all scores on the TJC and SJC-CRP, CRP(mg/dl), and PGA ≤ 1) and by SDAI(<3.3) were proposed by ACR/EULAR. Using patient reported outcomes as anchors, this analysis validated these remission criteria against traditional DAS28(using CRP <2.6)remission. **METHODS:** Efficacy of golimumab(GLM) was assessed in MTX-naïve RA patients(GO-BEFORE, N=637), RA patients with inadequate response to MTX (GO-FORWARD, N=444) and RA patients previously treated with biologic anti-TNF α agent(s) with baseline MTX use(GO-AFTER, N=305). Pooled data from patients who received placebo (PBO)+MTX, or GLM(50or100mg)+MTX, q4wks were used for this analysis. Patient reported outcomes were measured using: HAQ, SF-36 PCS and MCS, FACIT-Fatigue, and VAS 0-10 of impact of RA on daily work productivity. Descriptive statistics were provided for patient reported outcomes among patients in remission as defined remission definitions. **RESULTS:** Greater proportions of patients treated with GLM+MTX vs patients treated with PBO+MTX achieved remission by each remission definition. In the pooled analysis, the remission rate at wk24 was the highest(20.2%) by DAS28 vs remission by SDAI(10.6%, $p<0.001$) and remission by Boolean-based definition(8.6% $p<0.001$). Patients with remission by DAS28 achieved normal physical function(HAQ ≤ 0.5), normal SF-36PCS and MCS(≥ 50) by 67.8%, 38.4%, 62.2%, respectively; these parameters were numerically lower vs. patients with remission by SDAI(81.3%, 62.8%, 72.1%, respectively) or by Boolean-based definition(82.0%, 63.5%, 74.3%, respectively). Patients in remission by DAS28 had higher HAQ scores(0.43 ± 0.49) vs patients in remission by SDAI(0.26 ± 0.41) or Boolean-based criteria(0.28 ± 0.44). Similar results were observed in measures of FACIT-Fatigue and productivity VAS scores. Among MTX-naïve patients in GO-BEFORE who achieved remission by DAS28, 71.3% achieved normal physical function vs 86.9% of those in remission by SDAI and 86.5% of patients in remission by Boolean-based definition. Among anti-TNF α experienced patients in GO-AFTER, 62.1% of those in remission by DAS28 achieved normal physical function vs. 65.0% of those in remission by SDAI, and 66.7% of patients in remission by Boolean-based

definition. **CONCLUSIONS:** While disease remission has been adapted as a target in the management of RA, more stringent remission criteria proposed by ACR/EULAR can provide optimal patient-reported outcomes.

PMS53

USING SCATTER PLOTS, ANALYSIS OF UNIVARIATE RELATIONSHIP BETWEEN CONFOUNDERS AND OUTCOMES AMONG RHEUMATOID ARTHRITIS PATIENTS WHO INITIATED ANTI-TUMOR NECROSIS FACTORS AND SUBSEQUENTLY SWITCHED OR ESCALATED

Baser O¹, Schmeichel-mueller C², Ingham M²

¹STATinMED Research/The University of Michigan, Ann Arbor, MI, USA, ²Janssen Scientific Affairs, LLC, Horsham, PA, USA

OBJECTIVES: To examine the relationship of health care costs with baseline demographic and clinical characteristics for rheumatoid arthritis (RA) patients. **METHODS:** Adult RA patients (ICD-9: 714.XX) treated with anti-tumor necrosis factors (anti-TNFs) were identified from a large US commercial claims database (June 2004-June 2009). Patients who switched to another anti-TNF or escalated their dosage were identified between the initial anti-TNF date and June 2008. Total and RA-related health care costs were calculated during the 12-month period after switch or dose escalation. Scatter plots and box plots were drawn to examine the relationship between age, gender, comorbidity indexes, baseline costs and total all-cause and RA-related health care costs. **RESULTS:** A total of 2587 RA patients with a mean age of 55.9 were included in the final sample. 23.5% of these patients were insured by Medicare and 76.5% by commercial health plans. Scatter plots illustrate a slightly positive relationship between age and total health care costs in the commercial population. Moreover, a stronger positive trend exists between the Charleston Comorbidity Index (CCI) and total health care costs but not with RA-related health care costs in the commercial population. Chronic Disease Score (CDS) shows the same trend as CCI. A positive relationship can also be seen between baseline health care costs and follow up all-cause or RA-related costs. The majority of observations were clustered at the lower end of the domain. We further examined the relationships in the patient populations treated with and without methotrexate, and the results were similar. **CONCLUSIONS:** There were strong positive relationships between baseline and follow-up health care costs among RA patients who initiated anti-TNFs and subsequently switched to another drug or escalated their dosage. The positive relationships between CCI and CDS were more prominent in the commercially-insured patient population.

PMS54

ROUTINE ELECTRONIC PATIENT REPORTED OUTCOME (ePRO) DATA COLLECTION IN AN ORTHOPAEDIC OUTPATIENT CLINIC - METHODS USED TO ENSURE PROPER MIGRATION OF THE PRO MEASURE AND BENEFITS TO THE CARE PATHWAY

Harrington R¹, Churchman D², Dawson J³, Clayton D⁴, Price A¹, Rees J¹

¹Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), Oxford, UK, ²Isis Innovation Ltd., Oxford, Oxfordshire, UK, ³Health Services Research Unit, Department of Public Health, University of Oxford, Headington, Oxford, UK, ⁴PharmaQuest Ltd, Banbury, Oxfordshire, UK

OBJECTIVES: To develop and test an ePRO system for routine collection of surgical outcomes in a busy orthopaedic clinic. **METHODS:** We developed an ePRO (iPad) version of the widely adopted Oxford Knee (OKS) and Shoulder (OSS) scores. A multi-stage process was undertaken to ensure ePRO versus paper version equivalence involving the PRO instrument developer, PRO manager, PRO translation specialists as well as surgeons and Electronic Management Record (EMR) hospital specialists. This included, a review of the draft ePRO version; pilot-testing (cognitive debriefing and usability testing) on five patients attending an outpatients clinic; with pilot-tested results reviewed to ensure no issues arose during migration to ePRO. **RESULTS:** The ePRO version of both questionnaires were shown, from pilot-testing, to be easy to use. Compared with OKS and OSS paper versions, ePRO responses were all legible (an issue for some Rheumatoid patients) and complete. ePRO completion also takes care of data entry, resulting in a dataset free of errors that might otherwise arise. This suggested the potential for higher return rates with reduced handling costs. Following review of pilot-testing, no significant issues were identified, so the final ePRO versions were adopted. Secure synchronisation of the completed ePRO results with the local EMR system proved straight-forward, required little data cleaning and provided almost immediate feedback of outcomes to clinicians. **CONCLUSIONS:** Initial results demonstrated the OKS and OSS have been successfully migrated to the ePRO (iPad) version, with results from pilot-testing demonstrating that the validity of the original PRO instrument is retained. ePRO completion enters scores instantaneously on the local EMR system and as a result routine collection of a high volume of PROs could be achieved efficiently. This development facilitates the collection of PRO measure data within the clinic setting, highlighting their potential to enhance patient-centred care across the patients care pathway.

PMS55

QUALITY OF LIFE AMONG PATIENTS WITH SELF-REPORTED RHEUMATOID ARTHRITIS: A NATIONALLY REPRESENTATIVE SAMPLE

Rappaport H
 University of Louisiana at Monroe, Monroe, LA, USA

OBJECTIVES: To compare the health-related quality of life of patients with self-reported Rheumatoid Arthritis to statistically matched patients without Rheumatoid Arthritis. **METHODS:** The study utilized a cross-sectional population-based design, in which respondents, representing non-institutionalized adults in the United States of ages 18 or above, were chosen from the 2006 Medical Expenditure Panel Survey (MEPS). Respondents were included in the self-reported Rheumatoid